FARNAN LLP

January 10, 2019

VIA E-FILING

The Honorable Colm F. Connolly
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

[redacted]

RE: *Par Pharm. Inc., et al. v. Eagle Pharms. Inc.*, C.A. No. 18-cv-823-CFC

Dear Judge Connolly:

We write on behalf of Plaintiffs ("Par") in response to Eagle Pharmaceuticals, Inc.'s January 9, 2019 letter regarding entry of a protective order in above-captioned matter. Par respectfully requests that the Court enter a protective order in the form attached hereto as Ex. A, rather than the one proposed by Eagle. As Eagle notes, there are three disputed issues as between the parties' respective proposals (a redline showing the differences is attached as Ex. B).

Issues #1 and 2: Eagle's API supplier and Par's In-House Designees

A party seeking to restrict access to discovery materials must demonstrate "good cause" for the restriction. FED. R. CIV. P. 26(c); *In re Deutsche Bank Trust Co. Americas*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). "Good cause exists when disclosure will result in a clearly defined and serious injury to the party seeking the protective order." *U.S. v. Dentsply Int'l, Inc.*, 187 F.R.D. 152 (D. Del. 1999). Access to discovery materials by in-house counsel cannot be restricted simply based upon their status as in-house counsel. *U.S. Steel Corp. v. U.S.*, 730 F.2d 1465, 1468-69 (Fed. Cir. 1984). Rather, such restrictions are appropriate only to the extent there exists an *unacceptable* risk of inadvertent disclosure of the confidential information. *Id.* In assessing a proposed restriction, courts must weigh the risk of inadvertent disclosure or use of the information against the harm of imposing on a party's right to have the benefit of counsel of its choice, based on the specific facts presented in each particular case. *Deutsche Bank*, 605 F.3d at 1379-80; *Xerox Corp. v. Google, Inc.*, 270 F.R.D. 182, 184 (D. Del. 2010). "[T]he goals of full disclosure of relevant information and reasonable protection against economic injury are in tension and each must be fairly balanced against the other." *Boehringer Ingelheim Pharms., Inc. v. Hercon Lab. Corp.*, 18 U.S.P.Q. 2d (BNA) 1166, 1168 (D. Del. 1990) (citation omitted).

Here, the parties have agreed to several restrictions designed to protect against the risk of inadvertent disclosure or use of a party's confidential information, including the imposition of both a patent prosecution bar and an FDA bar (*see* Paragraph 2(k)). In addition, the parties have agreed to a two-tiered protective order, whereby materials designated as "Confidential" may be disclosed to up to two specified in-house counsel, but materials designated as "Highly Confidential" are to be treated as "Outside Counsel's Eyes Only." *See* Paragraph 5. "Highly Confidential" information is to be limited to specific categories of particularly sensitive, competitive business information. *See* Paragraph 2(c). Among other things, the parties have agreed that the commercial terms of any agreements between a party and its suppliers of active ingredients (API) shall be "Highly Confidential." Paragraph 2(c)(i).

Eagle seeks to further include the identity of its API supplier as "Highly Confidential." That goes too far. The potential suppliers of vasopressin API are limited, and their identities are

known. The FDA publishes a list of all Drug Master Files (DMFs) filed with it,[1] and there are only 6 vasopressin suppliers on that list. *See* Ex. C (DMF list filtered for vasopressin). Similar information is available from other public sources, including the API suppliers themselves. *See, e.g.,* Ex. D. Thus, there is nothing confidential about who the suppliers of vasopressin API are.

The identity of Eagle's API supplier, however, is important to this Hatch-Waxman Act ANDA litigation. The asserted patent claims include limitations relating to the identity and/or amount of vasopressin degradants present in the claimed compositions. *See* Ex. E (highlighted excerpts). Thus, Eagle's API supplier has information that will be highly relevant to infringement issues in this case. Moreover, as the supplier of a critical component of the accused drug products, Eagle's API supplier may be liable for contributing to and inducing Eagle's infringement of Par's patents. *See* 35 U.S.C. § 271(b), (c). Par's in-house counsel need to be involved in the decisions about these issues—i.e., the discovery to be sought from the API supplier and evaluating potential infringement claims against them, and they need to know the identity of the API supplier in order to do so. Par cannot be expected to subpoena or sue a party whose identity it does not know. Moreover, in-house counsel can provide important technical assistance to litigation counsel in terms of seeking and evaluating the discovery information obtained from the API supplier, and the identity of the API supplier cannot be hidden from them in that context.

Eagle's sole justification for including the identity of its API supplier as "Highly Confidential" information is the bare existence of Fresenius' allegations in a separate antitrust suit that Par took steps to prohibit its competitors from obtaining vasopressin API, even for purposes of submitting an ANDA. The very presence of this case, however, puts the lie to Fresenius' allegations—Eagle, a potential competitor of Par, obviously was able to obtain the vasopressin API necessary to prepare and submit its ANDA. Eagle does not allege that it had any difficulty finding an API supplier or that Par has done anything to interfere with its API supply. And indeed, there are two other generic manufacturers that have filed vasopressin ANDAs, both of which Par has sued for infringement (Sandoz, *see* D.N.J. 18-cv-14895, and Amphastar, D. Del. 18-cv-2032). Obviously, they too were able to secure the vasopressin API needed to file their ANDAs. The Fresenius allegations on which Eagle relies are vigorously disputed and demonstrably false.

Eagle says that in view of Fresenius' demonstrably false allegations it is "concerned about" the disclosure of its API supplier to Par's in-house counsel. Eagle does not specify what that concern is, but it is clearly a not-so-thinly-veiled assertion that Par's in-house counsel are untrustworthy. The protective order provides that confidential discovery materials may only be used for purposes of the present litigation, and no other purpose. Eagle is suggesting that Par's in-house counsel cannot be trusted with the identity of Eagle's API supplier because they would turn around and use that information to unlawfully interfere with Eagle's API supply. That suggestion defies Par's integrity and is unsupportable. The mere existence of unproven, vigorously disputed allegations that fly in the face of objectively verifiable facts is plainly insufficient to sustain Eagle's heavy burden of restricting access and cannot form the basis of depriving in-house counsel responsible for managing this case from having knowledge of information highly relevant to the litigation. *See, e.g., U.S. Steel*, 730 F.2d at 1468 ("Like retained counsel, however, in-house counsel are officers of the court, are bound by the same Code of Professional Responsibility, and are subject to the same sanctions."); *Boehringer*, 18 U.S.P.Q.2d at *2 (same).

[1] DMFs are FDA submissions filed by API suppliers that provide confidential detailed information about the manufacturing and characterization of the API they sell.

Eagle also objects, in particular, to Par's identification of Matthew Maletta, Chief Legal Officer, and Lawrence Brown, Vice President & Assistant General Counsel, IP, as its two in-house counsel designees. Eagle does not identify any reason why Messrs. Maletta and Brown cannot be trusted with knowledge of Eagle's confidential information, beyond unjustified speculation arising out of the mere existence of Fresenius' disputed and unproven antitrust allegations—none of which specifically relate to Messrs. Maletta and Brown. [redacted] Messrs. Maletta and Brown have stated they will comply with the obligations that would be imposed upon them by the protective order, and there is simply no basis for concluding that they cannot be trusted to do so.[2] Thus, the Court should overrule Eagle's objection to Par's designation of Messrs. Maletta and Brown as its designated in-house counsel.

Issue #3: Eagle's Proposed Exclusion to the FDA Bar It Proposed

The purpose of an FDA bar is to prevent inadvertent use of another party's confidential information in connection with the preparation of FDA submissions. They are sometimes entered in ANDA cases, but this court and others sometimes reject them. *See* Ex. F. Par is willing to live with or without one here, and it acquiesced to Eagle's insistence that one be included. Eagle seeks, however, to add an exclusion for a party's "own drug approval applications." Although facially neutral, for all practical purposes, that would only restrict Par. As a generic manufacturer, Eagle's FDA submissions will relate to seeking approval of the ANDA at issue here, such that the exclusion would swallow the whole with respect any anticipated FDA submissions by Eagle. Not so with respect to Par, whose product is already approved and who would be more likely to file Citizen's Petitions that applied generally to FDA approvals with respect to all vasopressin products. Par is willing to accept an FDA bar, but not one that binds only it and not Eagle. Eagle cites no case adopting its self-serving exclusion.

Eagle falsely asserts that Par's confidential information would be of no use in pursuing its ANDA. Vasopressin is a peptide that is unstable in aqueous solutions (like the products at issue), and Par suspects Eagle will have a difficult time overcoming a variety of technical hurdles in trying to meet the stringent FDA-approval requirements for such products. Having access to Par's confidential NDA and R&D materials, and seeing how Par was able to overcome those hurdles, would be immensely helpful to Eagle in trying to get its copycat product approved.

That Eagle is smaller than Par is also unavailing. The issue is the risk of inadvertent use of another's confidential information, and the size of the parties' legal departments has no bearing on their counsel's ability to compartmentalize information.

Therefore, Par requests the Court enter a protective order in the form attached hereto as Ex. A.

2 [redacted]

Respectfully submitted,

/s/ Michael J. Farnan

Michael J. Farnan

cc: All Counsel of Record (via E-Mail)